



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 7 1999

Food and Drug Administration
Rockville MD 20857

Rosemary Jacobs
Box 1033
Derby Line, VT **05830**

Re: **96P-0342/CP 1**

Dear Ms. Jacobs:

This responds to your citizen petition submitted on September 20, 1996, requesting that the FDA require promoters of products containing colloidal silver to:

- a) issue a statement explaining why their product should be bought and consumed;
- b) submit evidence to the FDA to substantiate the claims made in such a statement; and
- c) include a warning about argyria on the labels of products containing colloidal silver and in all promotional materials.

On August 17, 1999, the FDA published in the *Federal Register* (64 FR 44653) a final rule amending FDA's regulations in 21 CFR part 310. The Agency finds that this rule addresses your concerns regarding colloidal silver in human drugs and therefore considers your petition to be granted.

Under the new regulations, all over-the-counter (OTC) drug products containing colloidal silver ingredients or silver salts for internal or external use are not generally recognized as safe and effective. FDA will consider any OTC drug product containing colloidal silver ingredients or silver salts that is labeled, represented, or promoted for the treatment and/or prevention of any disease to be a new drug. Any new drug that is marketed without FDA approval is misbranded and subject to regulatory action.

To date, FDA has not approved a new drug application for any colloidal silver product. After September 16, 1999, any OTC drug product containing colloidal silver or silver salts that is introduced or delivered for introduction into interstate commerce and for which FDA approval has not been obtained is subject to regulatory action unless the product is under clinical investigation and the sponsor of the investigation is in compliance with FDA's regulations regarding investigational new drugs.

Sincerely yours,

Margaret Dotzel
Acting Associate Commissioner for Policy

Enclosure: Over-the-Counter Drug Products Containing Colloidal Silver Ingredients or Silver Salts; 64 FR 44653, August 17, 1999

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